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**SEALED
BY COURT ORDER**

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

THE UNITED STATES OF AMERICA,
ex rel. JANE DOE and JOHN DOE

Plaintiffs,

v.

SINGULEX, INC.

Defendant.

C V 16 5241

CIVIL ACTION

FILED IN CAMERA AND
UNDER SEAL

JURY TRIAL DEMANDED

RELATOR'S COMPLAINT

FILED
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CLERK OF COURT
NORTHERN DISTRICT OF CALIFORNIA
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1 1. On behalf of the United States of America, plaintiff-relators Jane Doe and John Doe
2 (“Relators”) bring this action against Defendant Singulex, Inc. (“Singulex” or “Defendant”) for
3 violations of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.* (hereinafter referred to as the
4 “Federal False Claims Acts”).
5

6 **I. SUMMARY OF THE ACTION**
7

8 2. This is an action to recover damages and civil penalties on behalf of the United States
9 arising out of Defendant Singulex’s submission of false and fraudulent claims for payment to
10 Medicare, Medicaid and other government health care programs for medically unnecessary lab tests.

11 3. Defendant Singulex is a clinical laboratory offering a menu of over 60 blood tests to
12 help physicians in the diagnosis and treatment of patients. The majority of Singulex’s tests are covered
13 by Medicare, so long as the tests are medically necessary for the diagnosis and treatment of the patient.
14

15 4. Starting in the Fall of 2015, Defendant began to devise a multi-faceted fraudulent
16 scheme to increase Medicare reimbursement for its lab tests, without regard to medical necessity. This
17 scheme was directed and orchestrated by Singulex executives. Internally, the scheme is called the
18 “Medical Necessity Coding Project,” however the purpose of the project is to increase profits through
19 enhanced reimbursements without regard to medical necessity and contrary to the project’s name.
20

21 5. As part of the fraudulent reimbursement coding scheme, Singulex carefully redesigned
22 its requisition form – a form used by physicians in ordering lab tests – to increase Singulex’s
23 reimbursement for the tests. This new and misleading form was launched in May 2016. In addition to
24 devising a new requisition order form, the Company’s top management exerted significant pressure on
25 the sales representatives and administrative staff (the “Physician Services Department” and the billing
26 department) to aggressively convey false coding information to providers. That is, upper management
27 instructed Singulex employees to instruct providers to falsely use certain diagnosis codes on the
28

1 requisition form, so that Singulex can receive reimbursement or higher reimbursement amounts from
2 Medicare for its lab tests. Relators are aware of several physicians who have rightly been angered and
3 outraged by this false coding advice, as it is solely within their medical judgment to select the
4 appropriate diagnosis codes for their patients.

5 6. Since the launch of the reimbursement coding scheme in May 2016, Singulex has
6 tracked its progress and internally touted its success. In an internal presentation on August 25, 2016,
7 the Vice President of Laboratory Operations Mark Stene boasted that for the first three months of the
8 project, Medicare reimbursements have increased by an extraordinary “6,000-13,000%.”

9
10 7. Defendants’ fraudulent billing practices have caused Medicare, Medicaid and other
11 government health care programs to pay false claims for medically unnecessary and/or miscoded lab
12 tests. At the expense of the government health care programs, Defendants have emphasized business
13 profits over compliance with the billing rules.

14
15 8. Singulex has been penalized for fraudulent conduct before. In April 2015, Singulex
16 entered into a settlement agreement with the government resolving allegations that it paid physicians
17 for lab referrals in violation of the Anti-Kickback Statute and for billing for medically unnecessary lab
18 tests as a result of the tainted referrals. Singulex also entered into a Corporate Integrity Agreement
19 (CIA) with the government which puts in to place procedures and reviews to promptly detect
20 fraudulent conduct. Despite this recent settlement and current CIA, Singulex is continuing its
21 fraudulent practices with the scheme described in this Complaint, in continued violation of the False
22 Claims Act as well as the CIA still currently in effect.

23 **II. JURISDICTION AND VENUE**

24
25 9. Jurisdiction is founded upon the FCA, 31 U.S.C. § 3732(a) and (b) and 28 U.S.C. §§
26 1331 and 1345.
27
28

10. Venue is proper in the Northern District of California under 31 U.S.C. § 3732(a) and (b) and 28 U.S.C. § 1391(b) and (c).

III. THE PARTIES

11. The United States is a plaintiff in this action, on behalf of the Department of Health and Human Services (“HHS”), the Centers for Medicare and Medicaid Services (“CMS”), and other federally funded government health care programs, including Medicaid, TRICARE, and the Veterans Administration. CMS, which is part of HHS, administers Medicare. Medicare is a government health insurance program for people age 65 or older, certain disabled people under age 65, and people of all ages with end stage renal disease. *See* 42 U.S.C. §§ 426 and 426A.

12. Medicare, the other federally-funded government health care programs and Medicaid are collectively referred to herein as “the Government Health Care Programs.”

13. Throughout the Relevant Time Period, the Government Health Care Programs have paid for Defendant’s laboratory tests.

14. Relator Jane Doe is a resident of the United States.

15. Relator John Doe is a resident of the United States.

16. Defendant Singulex, Inc. (“Singulex”) is a clinical laboratory incorporated in Delaware with its corporate headquarters and laboratory located in Alameda, California. Singulex currently offers more than 60 blood tests that primarily focus on the assessment of chronic conditions such as cardiovascular health, inflammation, diabetes, abnormal cholesterol, or hormone imbalances, as well as prostate cancer monitoring. Singulex offers five blood tests that apply its proprietary technology to measure cardiovascular health and inflammation.

17. Singulex is a privately-held company with a number of different investors. In May 2016, Grifols, an international healthcare company, invested \$50 million in Singulex for a 20% stake

1 in the Company. Some of the other investors in Singulex are Fisk Ventures LLC, a private venture
 2 capital fund; OrbiMed Advisors, a healthcare investment firm; JAFCO, a Japanese investment
 3 management company; and Prolog Ventures, a life science venture capital firm.

4 **IV. THE LAW**

6 **A. The Federal False Claims Act**

7 18. The Federal False Claims Act (“FCA”) provides, among other things, that any person
 8 who (1) “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or
 9 approval,” or (2) “knowingly makes, uses, or causes to be made or used, a false record or statement
 10 material to a false or fraudulent claim” is liable to the United States for a civil monetary penalty plus
 11 treble damages. 31 U.S.C. § 3729(a)(1)(A)-(B).
 12

13 19. The term “knowingly” means “that a person, with respect to information (1) has actual
 14 knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information;
 15 or (3) acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. §
 16 3729(b)(1)(A)(i)-(iii). Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).
 17

18 20. The term “claim” means “any request or demand, whether under a contract or
 19 otherwise, for money or property and whether or not the United States has title to the money or
 20 property, that (1) is presented to an officer, employee, or agent of the United States; or (2) is made to a
 21 contractor, grantee, or other recipient, if the money or property is to be spent or used on the
 22 Government’s behalf or to advance a Government program or interest, and if the United States
 23 Government (a) provides or has provided any portion of the money or property requested or
 24 demanded; or (b) will reimburse such contractor, grantee, or other recipient for any portion of the
 25 money or property which is requested or demanded” 31 U.S.C. § 3729(b)(2)(A)(i)-(ii).
 26
 27
 28

21. “[T]he term ‘material’ means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4).

B. The Law

1. Only Medically Necessary Tests Are Reimbursable

22. Tests and services provided to Medicare, Medicaid and other government health care program beneficiaries are only reimbursable if they are medically necessary. *See* 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1); Medicare Carrier’s Manual § 2049. That is, Medicare, Medicaid and other government health care programs only cover medical services that are “reasonable and necessary for the diagnosis or treatment of illness or injury.” *Id.* Accordingly, providers or labs may only submit claims for government reimbursement for “reasonable and necessary” medical tests and services, including lab tests.

23. Medicare Part B pays for clinical laboratory testing performed by companies such as Defendant Singulex. The laboratory performs testing on blood samples from patients referred to the laboratory by his or her physician. The laboratory – here Singulex – then submits claims to the government for payment.

24. As a condition of payment by Medicare, diagnostic laboratory tests must be ordered by a physician who is treating the beneficiary, that is, the physician who furnishes a consultation of treats a beneficiary for a specific medical problem. The physician must also use the results in the management of the beneficiary’s specific medical problem. 42 C.R.F. § 410.32(a).

25. The physician who orders clinical laboratory services “must maintain documentation of medical necessity in the beneficiary’s medical record.” 42 C.R.F. § 41032(d)(2).

26. The clinical laboratory submitting the claim to a Government Health Care Program must maintain documentation it receives from the ordering physician, as well as documentation that

1 the information that the lab submitted with the claim accurately reflects the information it received
 2 from the ordering physician. 42 C.F.R. § 410.32(d)(2)(ii).

3 27. During claims review, CMS may deny claims by laboratories where documentation
 4 provided does not demonstrate that the service is reasonable and necessary, or where the providers fail
 5 to provide documentation requested to establish medical necessity. 42 C.F.R. § 410.32(d)(3)(ii).

6 28. The entity submitting the claim my request from the referring physician additional
 7 diagnostic and other medical information to document that the services it bills are reasonable and
 8 necessary. If the entity requests additional documentation, it must request material relevant to the
 9 medical necessity of the specific test(s). 42 C.F.R. § 410.32(d)(3)(ii).

10 **2. The Laboratory Bills For and Receives Reimbursement for Lab Tests**

11 29. The majority of laboratory testing services are paid by Medicare on a fee-for service
 12 (“FFS”) basis. Medicare pays for most outpatient clinical laboratory services based on the Clinical
 13 Laboratory Fee Schedule in accordance with Section 1833(b) of the Social Security Act. The
 14 Medicare payment to the laboratory is the lesser of the laboratory’s actual charge, the local fee for a
 15 geographic area, or a national limit.

16 30. The clinical laboratory that provides the testing services bills the Government Health
 17 Care Programs directly, including Medicare. Medicare Part B pays approximately 80 percent of the
 18 Medicare-approved amount for these testing services.

19 31. The clinical laboratory must accept assignment of the Medicare beneficiary’s benefit in
 20 order to receive Part B payment for laboratory tests based on the Laboratory Fee Schedule. Medicare
 21 Claims Processing Manual, Ch. 16 – Laboratory Services, § 30.1 – Mandatory Assignment for
 22 Laboratory Tests. Thus, Par B deductible and coinsurance (co-payments) do not apply to laboratory
 23 services provided by a physician or by an independent laboratory. *Id.* § 30.3.

V. **BACKGROUND REGARDING LAB TEST ORDERING AND REIMBURSEMENT**

32. Physicians, using their independent medical judgment regarding each individual patient's medical needs, determine which lab tests are medically necessary for the diagnosis and treatment of the patient. The physician fills out the lab-provided order or requisition form by indicating on the form which lab tests should be run and also noting all applicable ICD-10 diagnosis codes justifying the tests. The number of tests ordered from a particular lab depends in part on the number of different labs used by the particular physician (as well as the patient's condition). If the physician only uses one lab for all tests (and the patient's condition warrants it), then the physician may select all or almost all of the lab tests offered by the lab.

33. Once the patient gets his/her blood drawn, the blood sample and requisition order form are shipped to the lab for assessment. The lab sends the patient's test results back to the patient's doctor.

34. The lab handles the submission of the billing to the patient's insurance. For Medicare billing, the lab would use the ICD-10 diagnosis codes selected by the physician to justify the medical necessity of the lab tests. The lab receives the Medicare reimbursement for the tests run with Medicare reimbursing about 80% of the Medicare approved reimbursement amount.

35. The majority of Singulex's tests are covered by Medicare. Certain state Medicaid Programs and other Government Health Care Programs reimburse for Singulex's tests as well. For example, in Singulex's "Wisconsin" territory (encompassing Wisconsin, Michigan and Minnesota), the average Medicare reimbursement is approximately \$265, and the average Medicaid reimbursement is approximately \$250 per physician test requisition. These are conservative averages which are based on claims submitted before the fraudulently billing scheme described herein was implemented by Singulex.

1 **VI. DEFENDANT'S FRAUDULENT LAB TEST REIMBURSEMENT CODING SCHEME**

2 36. In the Fall of 2015 Singulex launched a project specifically aimed at increasing
3 Medicare reimbursement for its lab tests. Internally referred to as the "Medical Necessity Coding
4 Project," it was a calculated and multi-faceted plan to illegally enhance Medicare reimbursement for its
5 lab tests. The purpose of this project was increased profits, without regard to medical necessity. This
6 fraudulent lab test reimbursement coding scheme has been and continues to be enormously successful
7 in increased Medicare reimbursement for Singulex.
8

9 37. The centerpiece of this project is a new, misleading requisition form to be used by
10 physicians for ordering its tests. And, to implement this plan, Singulex has mobilized sales
11 representatives from across the country as well as its Physician Services and Billing Departments.
12 Singulex has trained, incentivized and pressured these employees to give false coding advice to
13 physicians so that Singulex can enjoy increased reimbursement for its lab tests. Upper management of
14 the Company has designed and introduced this coding project to these employees and is intimately
15 involved in the push to make it successful.
16

17 38. Through the fraudulent scheme alleged herein, Singulex has usurped the physicians'
18 medical judgment and is directing the physician to specify particular ICD-10 diagnosis codes without
19 regard to the patient's medical condition so that it can receive higher reimbursement amounts for
20 performing the lab tests.
21

22 **A. Singulex's Misleading New Requisition Form**

23 39. In January 2016, Singulex began drafting a new requisition form to be used by
24 physicians in ordering Singulex's lab test. The redesigned form was to include the ICD-10 diagnosis
25 codes that support medical necessity and offer the highest reimbursements. In addition, Singulex
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1 worked on building an Accessioning database tool to increase ICD-10 coding. This tool is designed to
2 individually track and manage individual patient blood samples.

3 40. The initial focus of the new requisition form was geared towards Medicare patients and
4 enhanced reimbursement from Medicare. Eventually, the Company's plan is to concentrate on
5 commercial patients as well, but initially they focused their efforts on Medicare patients.

6 41. For reimbursement of lab tests, Medicare provides a list (often quite long) of all
7 "covered" ICD-10 diagnosis codes. ICD-10 codes are from the International Classification of
8 Diseases, Tenth Revision, Clinical Modification and are used to describe not only the patient's
9 diagnosis (if established), but also symptoms, signs and conditions. There are approximately 80,000
10 ICD-10 codes. CMS guidelines require use of ICD-10 diagnosis codes with the highest level of
11 specificity. The codes and order of codes (e.g., primary, secondary diagnoses) affect the amount of the
12 payment by CMS to the lab. *CMS Medicare Claims Processing Manual*, 20.2.2. CMS Manual, 100-4:
13 Transmittal 126, Sec. A - ICD-9-CM Diagnosis Codes.

14 42. In devising a new requisition form, Director of Laboratory Information Systems Gary
15 Jones and Information Technology Manager Charles Hewitt used Singulex's Laboratory Information
16 System to figure out which codes trigger the highest reimbursement, as well as which lab tests can
17 receive enhanced reimbursement. Jones and Hewitt produced a color-coded "cheat sheet" to illustrate
18 their work. They then used this information to build the new requisition form to get physicians to use
19 codes that will reimburse the highest amounts for testing. They put the "best" codes, i.e., the codes
20 which result in the highest reimbursement, on the front of the form.

21 43. The two key features of the new requisition to enhance reimbursement are:

22 **The 20 highest reimbursement codes are on the front of the new requisition form:**

23 From the approximately 80,000 possible ICD -10 codes, the new Requisition only lists 20
24 of the best reimbursement codes on the front of the form. These have been determined to
25 be the most profitable reimbursement codes.

Physician ranking of diagnoses is no longer possible: The new requisition form no longer includes a section for the physician to rank the primary, secondary and other diagnoses as the old form had. This allowed the Billing Department to manipulate the order of the codes in order to increase reimbursement for the tests. More specifically, the order of the primary, secondary and tertiary coding impact the dollar amount of the reimbursement.

44. Singulex “rolled out” the new requisition form at the National Sales Meeting in Dallas, Texas on February 9, 2016. Singulex’s approximately 25-plus sales representatives attended as well as upper management of the Company. At the meeting, Rebecca Farrell (Director of Marketing), Bob Brousseau (Vice President of Sales and Marketing), Mark Stene (Senior Vice President of Operations), and Gary Jones (Director of Laboratory Information Systems) all participated in a presentation regarding Singulex’s new requisition form for physicians ordering lab tests.

45. As part of the presentation, Ms. Farrell explained that they have been working on figuring out which ICD-10 codes reimburse the most for their tests, and that these codes are the ones listed on the new requisition form. To paraphrase, she stated that they have been “putting in a lot of work scrubbing the LIS [Singulex’s Laboratory Information System] and billing reimbursement to figure out which codes reimburse the most and those codes will be the codes that we are going to put on the new requisitions.”

46. Farrell also explained that the new requisition form would no longer have an area where the physician could rank the primary, secondary and tertiary diagnosis codes. When asked how the Singulex Billing Department was going to know which designated code was the primary, secondary or tertiary diagnosis (which affects the reimbursement for the test(s)), Ms. Farrell claimed not to know how the Billing Department was going to pick the order of the codes.

47. Singulex also announced at that same National Sales Meeting that all sales representatives would be given access to patients’ protected health information (PHI) in order to target physicians to order more Singulex lab tests. Vice President of Sales and Marketing Brousseau explained that the sales reps should review patients’ PHI so that they could tailor their sales pitches

1 about Singulex's lab tests to the physician's patients' medical conditions. This was presented as a
2 "direct marching order" to the field sales force. However, mindful of the potential HIPAA violations
3 in allowing the sales force access to all patients' PHI, Brousseau stated that the field representatives
4 were "on their own" with accessing this data and that Singulex would not defend any sales
5 representative if they were to get into trouble viewing and utilizing PHI to target physicians.
6

7 **B. New Requisition Form Rollout and False Coding Message**

8 48. On May 9, 2016, Singulex held a Webex conference call for the East and South East
9 Sales Regions to introduce the new requisition form. The call was led by V.P. of Marketing Farrell
10 and Sr. V.P. of Operations Stene. They explained that the new requisition form included the ICD-10
11 codes that were determined to pay the highest in reimbursement for Singulex's lab tests. They further
12 stated that the directive from V.P. of Sales and Marketing Brousseau was that the sales representatives
13 needed to physically destroy all prior versions of the requisition form and replace them with the new
14 form.
15

16 49. At the meeting, a sales representative inquired how the Billing Department would
17 determine primary, secondary and tertiary status of the codes now that the new form no longer
18 provided space for the physicians to rank them. Stene stated that "we think that billing uses a
19 combination to get reimbursement," i.e., he told the sales force that Singulex, not the doctor, would
20 determine the primary, secondary, and tertiary diagnoses.
21

22 50. The rollout of the new requisition form continued at the Regional Sales Meeting held in
23 Newark, New Jersey from May 16 – 18, 2016. All field sales representatives from both the East and
24 South East Regions were in attendance for this in-person meeting. Also in attendance in person were
25 V.P. of Sales and Marketing Brousseau, Compliance Office Patricia Ryan, Marketing Director
26
27
28

1 Rebecca Farrell. Attending via phone were the Director of Laboratory Information Systems Gary
2 Jones, IT Manager Charlie Hewitt and Senior V.P. of Laboratory Operations Stene.

3 51. Brousseau again explained to the sales representatives that the new requisition
4 contained the ICD-10 codes linked to the highest reimbursement for Singulex testing. He directed the
5 entire sales force in attendance that they are to instruct all providers to pick at least 3 of these codes on
6 the front of the new requisition.
7

8 52. Singulex's core products and services relate to cardiac testing. However, many of the
9 codes on the front of the form were, strangely, not cardiac codes. Field representatives John Carper
10 and Heidi Antonietti asked Brousseau what some of the codes meant that had nothing to do with
11 cardiovascular disease states. In response, Brousseau dismissively stated that "it doesn't matter what
12 the codes mean, you do not need to know what the codes mean, what you need to know is that you are
13 to tell the provider to pick at least 3 of the codes from the front of the requisition." There are codes on
14 the back of the form as well, but sales reps were instructed to direct doctors specifically to pick three of
15 the codes on the front of the form.
16

17 53. Sales representatives' commissions, which are a significant portion of their total
18 compensation, are in part dependent on the number of lab tests ordered by the physicians in their
19 territory. To that end, Brousseau stated that if physicians did not pick at least 3 codes from the front of
20 the new requisition form, the field sales force would see their commissions go down. Starting in
21 August 2016, management indicated that Singulex would start canceling or not performing requested
22 lab tests if the doctor had not selected the minimum three codes from the front of the form.
23

24 54. Singulex exerts significant pressures on all levels of the corporate hierarchy to deliver
25 the false coding message. In one instance, when upper management felt that the sales rep was not
26 adequately instructing a physician on choosing the codes preferred by Singulex, they called in the
27
28

1 Regional Director to deliver the false coding pitch and threatened that if the sales staff was unwilling
 2 to do it, they would call in the Director of Customer Operations “to get the job done.” This was
 3 discussed on a Regional Directors conference call on August 19, 2016 Specifically, Vice President of
 4 Sales and Marketing Bob Brousseau and Senior Vice President of Operations Mark Stene directed
 5 Kathy Marks, Southwest Regional Director of Sales, to have coding discussions with Dr. Gundry, a
 6 physician practicing in Southern California. That is, the Company executives directed Ms. Marks to
 7 instruct Dr. Gundry that when ordering a Singulex lab test, he needed to select at least three of the
 8 specified ICD-10 diagnosis codes from the front of the requisition form. If Ms. Marks were unwilling
 9 to convey these instructions to Dr. Gundry, then the executives stated that they would fly in Director of
 10 Customer Operations Laura Applegate to meet with the doctor and “get the job done.”
 11
 12

13 55. This call, and others like it, sent a clear message to Regional Sales Directors that they
 14 needed to carefully follow through with the false coding directive being implemented by the Singulex
 15 executive team.
 16

17 C. Training of Sales Representatives and Tableau Software

18 56. In order to further encourage doctors to pick the highest-reimbursing diagnosis codes,
 19 Singulex has provided a software program called Tableau to all sales representatives and Regional
 20 Directors. The Tableau software is loaded onto their iPads. It shows field sales representatives which
 21 codes the physicians are picking in ordering lab tests and which codes they could have picked to ensure
 22 that Singulex would obtain the highest reimbursement for performing the test. The list of codes that
 23 the rep should try to convince the provider to use on the requisition form is actually listed in the
 24 software.
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57. Brousseau directed all field representatives to receive training from IT Manager Charlie Hewitt on how to use the Tableau software to target physicians who are not selecting the highest reimbursed codes from the front of requisition form.

58. IT Manager Hewitt trained Relator Jane Doe on two separate occasions in June 2016 via Webex conference call. It is Relators' understanding that all of the Singulex sales representatives received similar training.

59. During these calls, Hewitt showed Relator how to look up all physician orders using the Tableau software to see which codes were picked by physician and which codes should have been picked to get the highest reimbursement. Hewitt indicated that when the physician does not select the highest-reimbursing codes, that is deemed an "error" in the Laboratory Information System. The LIS puts the test on "hold," and notifies the sales rep and the Physician Services department of the "error." Having been directed to correct such errors, sales reps and/or Physician Services reps then conduct the doctor's office to direct which codes to use to obtain more money for Singulex.

60. Hewitt provided very specific instructions as to the false coding advice for physicians (in addition to instructing that 3 codes from the front of the form must be checked):

- Singulex wants doctors to pick any of the diabetes codes because the diabetes codes reimburse for a lot of the testing;
- Singulex has 1 "Z" code on the requisition form that results in reimbursement from the government, so reps should tell doctors that if they are going to use a Z code, to use the one Singulex has on the requisition form; and
- Singulex wants the physicians specifically to select any E11 codes (the diabetes codes) and codes E78.0 (Pure Hypercholesterolemia) and E78.1 (Pure Hyperglyceridemia) because these are high reimbursement codes.

D. Role of Physician Services and the Billing Departments in the Reimbursement Scheme

61. Singulex has also mobilized the Physician Services and Billing Departments to advance the fraudulent lab test reimbursement coding scheme. Like the sales representatives, the Physician Services Department makes daily calls daily to physician's offices to obtain additional codes for increased lab test reimbursement. The Department's marching orders are the same as the sales reps' – get the physician to select at least 3 ICD-10 codes from the front of the requisition form as these are the best codes in terms of reimbursement.

62. The Physician Services Department is based at Singulex's headquarters in Alameda, CA. The Director of Customer Operations, Laura Applegate, oversees the Department. The employees are making approximately 20-50 calls a day trying to obtain higher-reimbursing codes.

63. Each day, the Physician Services Department receives an Excel spreadsheet list of physicians to call to request additional codes to be added to their patient's lab requisition form. Among other information, the list includes the provider's name, the patient identification number for the patient sample being analyzed by the requested lab tests (this number is referred to internally as "Accession"), and the Singulex employee assigned to call on the provider. This list is sometimes referred to as the LCD (limited coverage diagnosis) List.

64. While limited "educational" contacts with physicians are permissible, these calls go beyond educating physicians and instead effectively instruct physicians to falsely add ICD-10 codes to increase Singulex's reimbursement.

65. When Relator John Doe emailed Laura Applegate asking what the Physician Service reps were saying to the physician accounts over the phone, Applegate did not provide a full response in her written email. Instead, she picked up the phone and called him, stating that she could not put that message in email but could tell him over phone. She said that the Physician Services Department

1 representatives received the same message from management that management trained the sales
2 representatives on -- tell the providers that they need to pick at least 3 codes from the front of the form.

3 66. By way of a representative patient example, a 70 year-old Medicare patient visited her
4 health care provider, Nurse Practitioner Sharon Thurow, in Thiensville, Wisconsin in June 2016.
5 Nurse Practitioner Thurow requested approximately 45 Singulex lab tests, and listed the patient's
6 primary diagnosis as "Z00.00" which indicates an "encounter for general adult medical examination
7 without abnormal findings." Nurse Practitioner Thurow only checked one ICD-10 code (for Vitamin
8 D deficiency). This coding would have resulted in low reimbursement for Singulex performing a large
9 number of lab tests. As a result, Physician Services called the Nurse Practitioner Thurow. The ICD-10
10 code for "Pure Hypercholesterolemia," (a hereditary condition causing high cholesterol) was added,
11 which boosted the Medicare reimbursement to Singulex. This code was added purely to increase
12 Singulex's Medicare reimbursement for these 45 tests ordered for this patient.
13
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15 67. Relators further allege that the Physician Services Department sometimes does not even
16 call the physician's office but goes ahead and adds codes to the lab requisitions on their own without
17 any knowledge of the patient's condition or diagnosis. By way of example, on July 11, 2016,
18 Physician Services representative Elizabeth Canosa indicated that she had manually added an ICD-10
19 code to a physician requisition for a lab test for a Medicare patient in order to resolve the order in the
20 Laboratory Information System. Ms. Canosa specifically stated that she did this without contacting the
21 physician's office.
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24 68. Relators also alleged that Singulex's Billing Department sometimes calls physicians to
25 add reimbursement codes, or they simply add codes on their own, i.e., without even contacting the
26 doctors' office.
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69. The Excel spreadsheet list of providers (the Limited Coverage Diagnosis list) is also distributed by the Regional Sales Directors to their sales representatives so that the sales can target these physicians for additional codes as well.

E. Physician Complaints Regarding Singulex's Aggressive and Fraudulent Tactics

70. Singulex has angered many physician practices with constant calls asking for more billing codes. Physicians rightly view the selection of the applicable diagnosis codes for their patients as a task within their medical discretion and judgment, and not for a lab provider to dictate or control.

71. For example, when Physician Services representative Louie Batista calls the physician's practice, Thurow Primary in Thiensville, Wisconsin, to request more lab test codes, they often hang up on him. By way of another example, Dr. CigNo and Dr. Dornfeld in Ridgefield, Connecticut were very upset at the incessant phone calls from Singulex Physician Services asking for their practice to add more ICD-10 codes to patient samples sent in the previous days and expressed their dismay to the sales representative.

72. Singulex upper management is well aware of the numerous physician complaints. On a conference call with all of the Singulex Regional Directors on July 29, 2016, the Regional Directors notified V.P. of Sales and Marketing Bob Brousseau that there were many practices complaining about too many phone calls requesting codes and that they were pushing back and emphasizing that they are the medical doctors not Singulex.

73. Singulex is dismissive of these complaints and implies that it is the provider's fault when they will not agree to the addition of more codes to the lab requisition. Senior Vice President of Operations Mark Stene stated that "[f]or the most part [the] calls [requesting more codes] go well but there are times when offices are 'struggling' and may not be responsive."

F. The Fraudulent Lab Test Reimbursement Coding Scheme Has Been Extremely Profitable for Singulex

74. Since the launch of the scheme in May 2016, Singulex's Medicare reimbursements have grown enormously. Reimbursements are up by an extraordinary "6,000-13,000%."

75. The Company made this announcement touting the success of their "Medical Necessity Coding Project" at an internal "Town Hall" meeting on August 25, 2016. As part of a presentation by V.P. of Operations Mark Stene, he showed a PowerPoint slide setting forth the astonishing increase in Medicare reimbursement over the past three months since the scheme was implemented in May 2016. The Company is clearly tracking and analyzing the effect of their fraudulent reimbursement coding scheme. The PowerPoint slide shows the increase in Medicare reimbursement for three specific Singulex lab tests, Ferritin, HbA1c and NT-pro-BNP. In the first month alone (May 2016), Singulex received increased reimbursements for these three tests from 398-928%; in the second month (June 2016), reimbursements increased by 1421-2589% and in the last month (July 2016), they increased by an incredible 6,306-12,716%.

VII. COUNTS

COUNT I

FEDERAL FALSE CLAIMS ACT
31 U.S.C. §3729(a)(1)(A)

76. Relators repeat and re-allege each and every allegation contained in the paragraphs above as though fully set forth herein.

77. Defendant knowingly presented or caused to be presented a false or fraudulent claim for payment or approval in violation of 31 U.S.C. §3729(a)(1)[1986] and 31 U.S.C. §3729(a)(1)(A)[2009].

78. By virtue of the false or fraudulent claims that Defendant presented, the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT II

FEDERAL FALSE CLAIMS ACT **31 U.S.C. §3729(a)(1)(B)**

79. Relators repeat and re-allege each and every allegation contained in the paragraphs above as though fully set forth herein.

80. Defendant knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims to the United States Government in violation of 31 U.S.C. §3729(a)(1)(B)[2009].

81. By virtue of the false or fraudulent claims that Defendant caused to be presented, the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

REQUESTS FOR RELIEF

WHEREFORE, Relators, on behalf of the United States, demands that judgment be entered in their favor and against Defendant for the maximum amount of damages and such other relief as the Court may deem appropriate on each Count.

This includes, with respect to the Federal False Claims Act, three times the amount of damages to the Federal Government plus civil penalties of no more than Eleven Thousand Dollars (\$11,000.00) and no less than Five Thousand Five Hundred Dollars (\$5,500.00) for each false claim, and any other recoveries or relief provided for under the Federal False Claims Act.

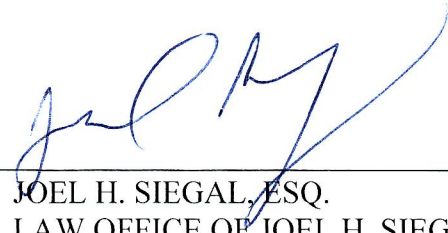
Further, Relators request that they receive the maximum amount permitted by law of the proceeds of this action or settlement of this action collected by the United States, plus reasonable

1 expenses necessarily incurred, and reasonable attorneys' fees and costs. Relators request that their
2 award be based upon the total value recovered, both tangible and intangible, including any amounts
3 received from individuals or entities not parties to this action.

4 **DEMAND FOR JURY TRIAL**

5 A jury trial is demanded in this case.

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8 Dated: Sept 9, 2016

By 
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